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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,322	07/20/2000	Assaf Govari	BIO-103	3443

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Philip S Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER
MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
3737	8

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/621,322	Applicant(s) GOVARI, ASSAF
	Examiner Eleni Mantis Mercader	Art Unit 3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

Response to Arguments

1. Applicant's arguments filed on 2/24/2003 have been fully considered but they are not persuasive. Responses to all the arguments are set forth in paragraphs 2-3, below.

2. Contrary to Applicant's arguments, Acker'032 teaches a method for calibrating a medical system by accounting for a metallic object/sensor within the mapping volume of the system and teaches calibrating this sensor placed within the mapping volume.

With respect to claims 1-7 and 10-19, the Applicant stated:

> With respect to the calibration method described in Acker, it is important to note that there is absolutely no specific teaching, suggestion or inference related to a method for calibrating a method system that includes accounting for a metallic object placed within the mapping volume of the system. Moreover, the method and algorithm described in Acker is directed toward calibrating the reference assembly 50 of the system. This is entirely different than the calibration method in accordance with the present invention that not only accounts for metallic objects within the mapping volume of the system, but also is directed to the calibration of the sensor placed within the mapping volume and subjected to a series of novel steps to include an interpolating step and an error limit comparison step (claim 1) and an extrapolating step and error limiting step (claim 11).

Applicant is invited to view in Figure 1, the surgical catheter (20) having a proximal end (22) and a distal end (24), wherein the probe body (28) incorporates a probe field transducer or position sensor (30) which, is physically connected to the distal end (24) of the catheter (see also col. 5, lines 57-62).

The two major issues presented by Applicant are: (1) whether extrapolation and interpolation are used in order to calibrate the location and orientation of the surgical catheter having a transducer or position sensor and (2) whether the transducer or position sensor is a metallic object. These issues are addressed in order.

(1). Extrapolation and interpolation are taught in order to calibrate the location and orientation of the surgical catheter having a transducer or position sensor

Figure 4 of Acker'032 shows a calibration method for the medical system wherein a reference field transducer radiator such as 100C is activated and its disposition with respect to the assemblies 50A and 50B can be determined (col. 9, lines 9-67 and col. 10, lines 1-5), by using an iterative process of comparing actual and measured values of the positions to determine an acceptable error yield (col. 9, lines 11-67 and col. 10, lines 1-6).

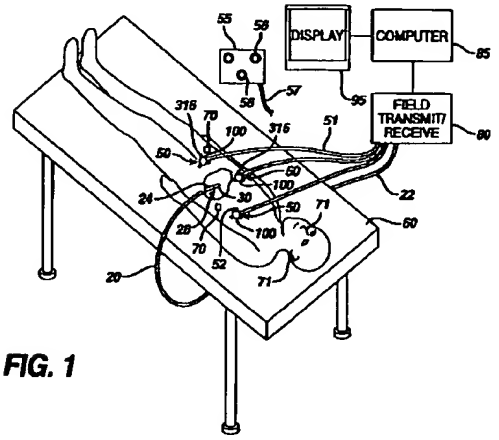
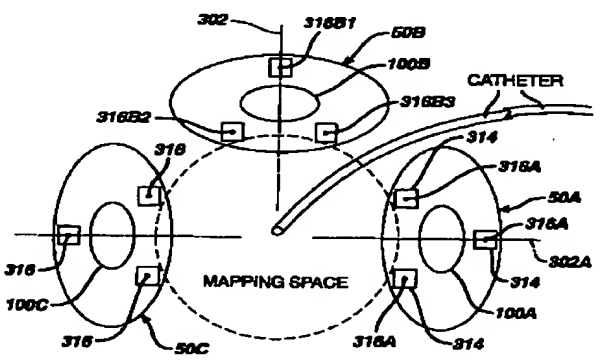


FIG. 1

FIG. 4



Figures 1 and 4 of Acker'032 is reproduced here for Applicant's convenience

Applicant's attention is particularly invited, to Figure 4, wherein the probe field transducer within the mapping field space can be utilized in the calibration step when the movable field transducer is placed in the various calibration sockets (314) at known positions, and by moving the probe tip (28) from socket to socket, the same method is applied of providing an iteration procedure for calibration that is within an acceptable error rate and wherein the probe field transducer replaces the calibration transducers (see col. 13, lines 6-18). Since there are three reference assemblies (50A, 50B and 50C), necessarily one of them will be at an

intermediate position. For example, the calibration sockets of 50B are at an intermediate location between 50A and 50C where the probe tip is touched and located, and an iterative process is performed as stated above, to establish an accepted error limit. In addition, Acker'032 teaches that the reference field transducers (100A, 100B and 100C) can themselves be calibration transducers and if coil 100A is energized, the field can be detected by reference field transducers 100B and 100C (see col. 10, lines 24-30).

Therefore, Acker'032 teaches that the probe field transducer/sensor when placed in the socket 314 of assembly 50A, can detect the magnetic fields transmitted by assemblies 50B and 50C, and the measured position of the probe on the basis of the detected fields can be compared with respect to the actual position of the socket wherein the probe was placed, and a determination can be made based on how the measurement compares to the estimated value and if it falls within the accepted error limit. The whole procedure is an extrapolation based procedure because estimations are determined from the known locations of the transducers or assemblies of interest (see col. 8, lines 64-67; col. 9, lines 1-67; col. 10, lines 1-30; wherein estimation procedures are discussed). Furthermore, as discussed above, when the position and orientation of the probe placed on assembly 50B is estimated with respect to the assemblies 50A and 50C, the whole procedure is necessarily an interpolation since the position of assembly 50B is intermediate or in-between assemblies 50A and 50C.

(2). The transducer or position sensor is a metallic object

The coils used in the system including the one in the probe used as a sensor is stated in Acker'032 to be as those produced by MINCO (see col. 6, lines 29-45).

The MINCO coils, which as described in Acker'032, typically used as heater coils are made out of metals. Therefore, Acker'032 by teaching use of a MINCO coil as a catheter sensor, inherently teaches a sensor which is a metallic coil/object.

3. With respect to claims 8-9 and 20-21, the Applicant stated:

> The Applicant would like to point out that this reference is directed toward a particular robotic surgical system only and does not in any manner address a robot controlled calibration system for calibrating a sensor.

The Examiner used Glassman et al.'401 solely for the teaching of using a robot to manipulate the medical probe of interest in order to automate medical procedures (see col. 2, lines 18-46) and hence a skilled artisan at the time that the invention was made would have known to use a robot for any medical procedure of interest including a calibration procedure as taught by Acker'032 in order to automate the particular calibration procedure.

Therefore, the Examiner agrees that Glassman et al.'401 do not teach a calibration procedure, because the Examiner did not use Glassman et al.'401 for that teaching. Instead, the Examiner used Glassman et al.'401 for the teaching that automation via use of a robot would have been obvious to a skilled artisan at the time that the invention was made to automate any medical procedure of interest including the calibration method as taught by Acker'032.

4. The 112 2nd paragraph rejection was overcome by the amendment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-7 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker'032.

Acker'032 teaches all the features of the instant invention including the use of a medical probe being introduced within a magnetic field, aligning the sensor incorporated in the probe within the mapping volume and performing a calibration method correcting for any errors on the basis of a calibration procedure, wherein the calibration is repeated though-out the mapping volume (see Figure 1 and Figure 4; also see col. 5, lines 56-67 and col. 6, lines 1-28; referring to a sensor 30 included in a medical probe which detects magnetic fields and col. 10, lines 7-67 and col. 11, lines 1-19; describing the calibration procedure within the magnetic field).

Acker'032 does not specifically teach the mathematical formula for calibration as claimed in the instant invention. However, it would have been obvious to one skilled in the art at the time that the invention was made to have used a functional equivalent of such a calibration as used in Acker'032 which would determine the calibration on the basis of the difference between the expected and actual measurement and make a determination as to an acceptable error limit, as these constitute calibration procedures well within the knowledge of skilled artisans. In comparing Figures 1 and 4 of Acker'032 with Figures 1 and 2 of the instant invention, it is evident that the dimensions of the mapping areas are comparable.

The coils used in the system including the one in the probe used as a sensor is stated in Acker'032 to be as those produced by MINCO (see col. 6, lines 29-45). The MINCO coils, which as described in Acker'032, typically used as heater coils are made out of metals.

Therefore, Acker'032 by teaching use of a MINCO coil as a catheter sensor, inherently teaches a sensor which is a metallic coil/object.

7. Claims 8-9 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker'032 as applied to claims 7 and 19 above, and further in view of Glassman et al.'401.

Acker'032 does not teach the use of the robot for manipulating the calibration of the procedure by moving the medical probe incorporating the sensor.

In the same field of endeavor, Glassman et al.'401 teaches the use of a robot to manipulate the medical probe of interest in order to automate medical procedures (see col. 2, lines 18-46).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Acker'032 and incorporated the teaching of Glassman et al.'401 to carry out the calibration procedure of the medical probe of interest as that would automate the calibration procedure.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Walker'112 teaches use of RTD sensors having a thin metal wire 62 as those produced by MINCO (see in particular col. 4, lines 28-54).

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3590 for regular communications and 703 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

Eleni Mantis Mercader
Examiner
Art Unit 3737

EMM
May 19, 2003